

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC., Defendant.)	DEMAND FOR JURY TRIAL
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs,)	<div style="background-color: black; height: 1.2em; width: 100%;"></div>
v.)	<div style="background-color: black; height: 1.2em; width: 100%;"></div>
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter Defendants.)	

**PLAINTIFF’S MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 5
REGARDING NO INEQUITABLE CONDUCT**

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Dated: December 11, 2023

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I INTRODUCTION

The Court should grant summary judgment in favor of plaintiff Nippon Shinyaku Co., Ltd. (“NS”) regarding Sarepta Therapeutics, Inc. and the University of Western Australia’s (together, “Sarepta”) counterclaim and defense of unenforceability of NS’s patents due to inequitable conduct (Counterclaim VI and Fifteenth Defense of the Second Amended Answer and Counterclaims, D.I. 328) because Sarepta has not identified any evidence supporting the requisite intent to deceive, and also because the allegedly withheld data and references cannot be but-for material to patentability as a matter of law.

II CONCISE STATEMENT OF FACTS

NS incorporates by reference its concise statement of facts (“SOF”) filed contemporaneously herewith.

III. SUMMARY OF THE ARGUMENT

The Court should grant summary judgment in favor of NS Sarepta’s counterclaim and defense of inequitable conduct because:

1. Sarepta has not identified any evidence from which an intent to deceive is the single most reasonable reference that can be drawn.
2. Additionally, the allegedly withheld data and references cannot be but-for material to patentability as a matter of law.

IV. ARGUMENT

NS is entitled to summary judgment of no inequitable conduct because Sarepta has identified no evidence supporting the requisite intent to deceive. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (“To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the [US]PTO” with clear and convincing evidence.). The “specific intent to deceive must be the

single most reasonable inference able to be drawn from the evidence.” *Id.* at 1290 (citation and internal quotes omitted).

The only evidence Sarepta has adduced concerning deceptive intent shows, at best, that named inventors Youhei Satou and Naoki Watanabe knew of additional data and the Sazani 2010 reference, that data and reference were not submitted to the PTO during prosecution of the NS patents, and someone should have known that information was material. *See* SOF ¶ 1. This is insufficient as a matter of law. *Therasense*, 649 F.3d at 1290. Other reasonable interpretations of Sarepta’s evidence is that the data and the Sazani 2010 reference were considered cumulative, as discussed further below, or irrelevant to the claims.

Separately, NS is entitled to summary judgment because it is undisputed that: (i) any data allegedly withheld was cumulative; (ii) there is no evidence that NS’s unexpected superiority argument was but-for material to patentability; and (iii) the Sazani 2010 reference is cumulative. Therefore, Sarepta’s bases for arguing inequitable conduct cannot be but-for material to patentability as a matter of law.

As a preliminary matter, Sarepta’s expert on PTO practice and procedure Andrew Hirshfeld did not provide an affirmative expert report concerning the materiality of the allegedly withheld information or misleading argument. SOF ¶ 2. Instead, Sarepta relies entirely on Dr. Dowdy’s opinions to support the materiality of that information. *See id.* However, Dr. Dowdy is a technical expert who is not qualified to opine on materiality in the context of inequitable conduct, as discussed in NS’ *Daubert* Motion to Exclude Testimony and Opinions of Steven F. Dowdy, Ph.D., filed contemporaneously herewith. Accordingly, Sarepta has adduced no reliable evidence whatsoever concerning the materiality of the withheld information or misleading argument.

[REDACTED]

[REDACTED]

[REDACTED] SOF ¶ 9. As to the former, [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] As to the latter, [REDACTED]

[REDACTED]

[REDACTED] SOF ¶ 10. Thus, omitted data points were cumulative to information showing a lack of superiority that was before the examiner, and were not material as a matter of law. Further, there is no evidence that the examiner credited NS's unexpected superiority argument in allowing the claims of the '361 Patent. In fact, the examiner expressly rejected NS's unexpected superiority argument, finding the arguments "not persuasive," and maintained his rejection of the claims because "[t]he compounds function as designed, to alter splicing." SOF ¶ 6.

After this rejection, NS: (i) made a narrowing amendment to delete the SEQ ID from claim 1 that fell within the prior art AO; (ii) made a new argument in support of patentability of the amended claims; and (iii) reiterated the previously-rejected unexpected results argument. SOF ¶ 7. The examiner then allowed the claims without providing stated reasons for allowance. SOF ¶ 8. [REDACTED]

[REDACTED] SOF ¶ 8. In other words, the previously-rejected unexpected results argument was not the sole reason for allowance. Therefore, even accepting, *arguendo*, that the omitted data points were non-cumulative to the data in the specification, speculation that the

Examiner was persuaded in part by the unexpected results argument or purported lack of data cannot establish either intent to deceive or but-for materiality. *Therasense*, 649 F.3d at 1290-91 (“when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found”).

Dr. Dowdy asserts that the Sazani 2010 reference is material to patentability because it: (i) “disclosed the entire chemical structure of AVI-4658, including the PMO chemical backbone and 5’-TEG modification”; and (ii) “provided detailed safety and genotoxicity information that was not otherwise available.” SOF ¶ 11. As discussed above, Dr. Dowdy is not qualified to opine on materiality in the context of inequitable conduct. From a technical perspective, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] SOF ¶¶ 12-13.

[REDACTED]

[REDACTED]

[REDACTED] *Id.* Likewise, the examiner concluded that the 5’ end modifications “recited in the claim were well known and routinely used in the art.” SOF ¶ 4. Both the examiner’s conclusions [REDACTED] support the inference that the 5’ TEG modification disclosures in Sazani 2010 were already well known in the art, and, in particular, were known to the examiner, rendering them undisputedly cumulative and precluding a finding that Sazani 2010 was but-for material.

[REDACTED]

[REDACTED] SOF ¶ 12. In rejecting the claims during prosecution of the ’361 patent, the examiner asserted that “[t]he invention includes modifications to the [antisense] compounds where

these modifications are well known and routinely utilized in the antisense art at the time of invention” and specifically noted the disclosure that “[t]he advantage of a PMO is that it has excellent safety profiles. . . .” SOF ¶ 4. Again, as above, the undisputed evidence supports an inference that the examiner was already aware that PMOs were safe rendering Sazani’s safety disclosures cumulative and precluding a finding of but-for materiality.

Finally, disclosures specific to AVI-4658 in Sazani 2010 are irrelevant to the patentability of the NS patent claims. AVI-4658 is an AO targeting exon 51 and is undisputedly not covered by the NS patent claims, which are exclusively directed to exon 53.

For the foregoing reasons, the Court should grant partial summary judgment in favor of NS on Sarepta’s counterclaim and defense of unenforceability.

Dated: December 11, 2023

Respectfully submitted,

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